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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/529,655 | 11/28/2006 | Matthew J. Scanlan | L0461.70156US00 | 5836 |

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| EXAMINER | |
|---|---|
| AEDER, SEAN E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/529,655 | SCANLAN ET AL. | |
| | Examiner | Art Unit | |
| | Sean E. Aeder | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1,2,5,10,11,14-18,27,47,64,69,76,91,106,120,130 and 143 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,5,10,11,14-18,27,47,64,69,76,91,106,120,130 and 143.

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5, 10, 11, and 120, as specifically drawn to nucleic acid molecules selected from the group consisting of (a) complements of nucleic acid molecules which hybridize under high stringency conditions to a nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of nucleotide sequences set forth as SEQ ID NOs: 1-14 and 97-108 and which code for a sarcoma associated antigen, (b) nucleic acid molecules that differ from the nucleic acid molecules of (a) in codon sequence due to degeneracy of the genetic code, (c) complements of (a) and (b), and (d) variants thereof.

Group II, claim(s) 14, 15, and 64, as specifically drawn to polypeptides encoded by the nucleic acids comprising a nucleotide sequence that is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group III, claim(s) 16 and 17, drawn to an isolated binding polypeptide that selectively binds to polypeptides encoded by the nucleic acids comprising a nucleotide sequence that is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group IV, claim(s) 18, drawn to a method of diagnosing cancer comprising determining the presence of an antibody that binds to one or more antigens encoded by a nucleotide sequence that is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group V, claim(s) 27 and 47, as specifically drawn to methods of diagnosing cancer, determining the onset of cancer, determining the progression of cancer, and determining the regression of cancer comprising determining the expression of an antigen or a nucleic acid that encodes said antigen, wherein the nucleic acid is at least

about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group VI, claim(s) 69, drawn to a kit comprising one or more binding agents that specifically bind to an antigen or the nucleic acid encoded by said antigen wherein said nucleic acid is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group VII, claim(s) 76, drawn to a method for treating a subject comprising administering an effective amount of an antibody or antigen-binding fragment thereof that specifically binds to and antigen encoded by a nucleotide sequence that is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group VIII, claim(s) 91, drawn to a method for treating a subject comprising administering an agent that selectively binds to an antigen or a nucleic acid encoding said antigen, wherein said nucleic acid is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group IX, claim(s) 106, drawn to a method for treating a subject comprising administering an agent which stimulates an immune response to an antigen encoded by a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group X, claim(s) 130, drawn to an agent which stimulates an immune response to an antigen encoded by a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

Group XI, claim(s) 143, drawn to an agent that selectively binds to an antigen or a nucleic acid encoding said antigen, wherein said nucleic acid is at least about 90% identical to a nucleotide sequence selected from the group consisting of SEQ ID NOs:1-14 and 97-108.

The inventions listed as groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-XI appears to be that they all relate to the special technical feature of nucleic acid molecules selected from the group consisting of (a) complements of nucleic acid molecules which hybridize under high stringency conditions to a nucleic acid molecule comprising SEQ ID NO: 1 and which code for a sarcoma associated antigen, (b) nucleic acid molecules that differ from the nucleic acid molecules of (a) in codon sequence due to degeneracy of the genetic code, and (c)

complements of (a) and (b). Note that the term "complement" broadly encompasses partial complements. A complement of a nucleic acid molecule shares as few as a single complementary base with said nucleic acid molecule.

However, Laprevotte et al (Journal of Virology, June 1984, 50(3): 884-894) teaches a nucleic acid molecule that is a complement of a nucleic acid molecule which would hybridize under high stringency conditions to a nucleic acid molecule comprising SEQ ID NO:1 and which codes for a sarcoma associated antigen (see Figures 2-3, in particular).

Therefore, the technical feature linking the inventions of groups I-XI does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Accordingly, groups I-XI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

***Species***

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1, 2, 5, 10, 11, 14-18, 27, 47, 64, 69, 76, 91, 106, 120, 130, and 143 are generic to a plurality of disclosed patentably distinct species of **sarcoma associated antigen sequences**. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The species represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. A single species is to be identified by a single SEQ ID NO for claims 1, 2, 5, 10, 11, 14-17, 27, 47, 69, 76, 91, 106, 120, 130, and 143. Further, a single species is to be identified by one SEQ ID NO or a specific combination of SEQ ID NOs for claims 18 and 64. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 69, 91, and 143 are generic to a plurality of disclosed patentably distinct species of methods comprising "**agents**" that bind "**a sarcoma-associated antigen or the nucleic acid molecule that encodes it**". The specification discloses said agents can be antibodies or polynucleotides. Applicant must elect a single "agent" and whether the elected method is to comprise binding a sarcoma-associated antigen or the nucleic acid molecule that encodes it. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents and/or response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 27 and 47 are generic to a plurality of disclosed patentably distinct species of methods comprising determining expression of "**a sarcoma-associated antigen or a nucleic acid molecule that encodes it**". Applicant must elect the species wherein expression of a sarcoma-associated antigen is determined *or* a method wherein expression of a nucleic acid encoding a sarcoma-associated antigen is determined. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents and/or response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Claims 106 and 130 are generic to a plurality of disclosed patentably distinct species of methods comprising administering an "**agent**". The specification discloses said agents can be antibodies or polynucleotides. Applicant must elect a single "agent". The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The methods of the above species differ at least in objectives, method steps, reagents and/or response variables, and criteria for success such that one species could not be interchanged with the other. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also

identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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